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EXAMINER	
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ART UNIT	**PAPER NUMBER**
1651	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/009,527	SCHAEFER ET AL.	
	Examiner	Art Unit	
	Lora E. Barnhart	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 June 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *36-39 and 41-68* is/are pending in the application.

4a) Of the above claim(s) *45-66* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *36-39,41-44,67 and 68* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendments

Applicant's amendments filed 6/26/07 to claim 36 have been entered. No claims have been cancelled. Claim 68 has been added. Claims 36-39 and 41-68 remain pending in the current application, of which claims 36-39, 41-44, 67, and 68 are being considered on their merits. Claims 45-66 remain withdrawn from consideration at this time. Prior art references not included with this Office action can be found in a prior action.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 36-39, 41-44, 67, and 68 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 36 as amended is drawn to a biological *in vitro* joint construct having a joint side and an opposed anchor side, wherein the two sides are "interlockingly connected *in vitro*" to each other. This limitation is confusing because it appears to be an attempt to recite a product-by-process. As currently drafted, the claim is not in proper product-by-process form. The previous version of claim 36 required that the sides be "connected," but it is not clear how this amendment changes the scope of the claim, if at all. Clarification is required.

Furthermore, the claim has been amended to require that "a first biocompatible material of the joint side" be connected to "a second biocompatible material of the anchor side," but it is not clear how these first and second materials relate to the overall physical and structural configuration of the claimed product. It is also not clear whether the cartilage and bone cells are cultured on these materials or not. Clarification is required. The claim should particularly point out each component of the claimed product and define the structural and physical relationships among all of the components.

Because claims 37-39, 41-44, 67, and 68 depend from indefinite claim 36 and do not clarify these points of confusion, they must also be rejected under 35 U.S.C. 112, second paragraph.

Furthermore, claim 68 requires that the connection in claim 36 be "by fibrin adhesion," which is confusing. Claim 36 does not require that the composition comprise fibrin, and claim 68 does not distinctly claim the manner in which the fibrin is physically and structurally related to the rest of the composition. It is not clear whether claim 68 requires the composition of claim 36 to further comprise fibrin. Clarification is required.

In general, applicant seems to be attempting to describe the claimed product by describing the manner in which it is made. This end is properly accomplished by a product-by-process claim (see M.P.E.P. § 2113) and may require a substantive evidentiary showing that the composition made by the process steps is distinct from the same composition made in a different way.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 36, 38, 41, 42, 44, 67, and 68 are/remain rejected under 35 U.S.C. 103(a) as being unpatentable over Itay (1991, U.S. Patent 5,053,050) taken in view of Mikos (1996, U.S. Patent 5,522,895), Rosenthal et al. (1995, U.S. Patent 5,466,462), and Jakob et al. (WO 99/21497; and German-to-English translation). Regarding Jakob et al., the page and paragraph numbers in this rejection refer to the English translation, which was made of record 10/24/05.

Itay teaches a composition produced *in vitro* that comprises a biocompatible carrier material (*e.g.* a fibrin matrix) and chondrocytes that have been expanded and enriched in culture medium; the composition may be implanted into defective bones

(Examples 1-3 and The Process). The composition of Itay can be produced in any shape, including cylindrical shapes (column 4, line 68) and the particular shape of the damaged area (column 5, lines 3-4), and in any size (Example 3). Because the composition of Itay comprises a fibrin matrix, Itay teaches fibrin adhesion.

Itay does not teach an *in vitro* composition comprising both cultured cartilage cells and cultured bone cells, said composition comprising cartilage cells on one face thereof and bone cells on the opposing face.

Mikos teaches seeding osteoblasts in growth medium onto a biodegradable polymer (column 4, lines 23-29), allowing the suspension to wick into the polymer foam (lines 29-33), and culturing the cells on the polymer to allow them to attach to the foam (lines 35-55). Mikos teaches that the culturing step allows the osteoblasts to secrete their own extracellular matrix, facilitating cell attachment and gradually eliminating the need for the polymer foam (column 4, lines 46-51). Mikos teaches that biodegradable polymers that form fibers are known in the art and include polyglycolic acid (column 3, lines 30-47). The composition of Mikos may take any desired anatomical shape according to the mold used to shape the polymer (column 3, lines 48-62).

Rosenthal et al. teach that fibrin and polyglycolic acid are functional equivalents in the tissue engineering and wound healing arts (column 1, lines 15-23).

Jakob et al. teach a composition comprising both a bone side and a cartilage side; the composition of Jakob et al. is a column of tissue that has been removed from a donor site at the articular face of a bone (page 2, paragraph 3; Figures 1, 5-7, 9, and 10). Jakob et al. also teach a composition comprising cartilage cells cultured *in vitro* on

bone-replacement material (page 5, paragraph 3; page 16, paragraph 3; Figures 11 and 12). The composition of Jakob et al. may have a circular cross-section (page 11, paragraph 4; page 12, paragraph 4; and Figures 13-16) or may have any shape (page 15, paragraph 3).

It is noted that claim 36 recites "consisting essentially of." M.P.E.P. § 2111.03 clearly indicates that the transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. *In re Herz*, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976) (emphasis in original). For the purposes of searching for and applying prior art under 35 U.S.C. §§ 102 and 103, **absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising."** If an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. *In re De Lajarte*, 337 F.2d 870, 143 USPQ 256 (CCPA 1964) *et al.* Since the specification in this case does not particularly point out the basic and novel characteristics of the claimed composition, "consisting essentially of" in claim 36 has been interpreted as "comprising" for the purpose of art rejections. Furthermore, as discussed in a previous Office action, the claim limitations "cartilaginous substance" and "bone substance" are not provided with limiting definitions (see page 5, lines 11-17 and 21-29 of the as-filed specification);

rather, these terms include all non-cellular components of cartilage and bone, respectively. It is not clear what components may and may not be included in the claimed composition without materially affecting its basic and novel characteristics.

A person of ordinary skill in the art would have had a reasonable expectation of success in combining the *in vitro* cartilage construct of Itay and the *in vitro* bone construct of Mikos because Rosenthal et al. teach that the biodegradable polymers on which each construct is based are functional equivalents for each other; therefore, the cartilage construct of Itay could be modified to include bone cells on one side, and the bone construct of Mikos could be modified to include cartilage cells on one side. The skilled artisan would have been motivated to combine the teachings of Itay and Mikos because Jakob et al. teach that compositions that have bone tissue on one side and cartilage tissue on the opposite side provide efficient repair of defects on the articular face of bone joints (page 15, paragraph 2, *inter alia*).

It would therefore have been obvious to a person of ordinary skill in the art at the time the invention was made to combine the *in vitro* bone construct of Mikos and the *in vitro* cartilage construct of Itay to yield a composition comprising cultured cartilage on one side and cultured bone on the opposite side because Jakob et al. teach that compositions so configured may be implanted into the articular portions of bones to effectively treat defects.

Therefore, the invention as a whole would have been *prima facie* obvious to a person of ordinary skill at the time the invention was made.

Applicant's arguments include an admission on the record that the claimed composition "mimics Jakob's et al.'s [*sic*] natural bone graft" at page 9, paragraph 5, of the reply; and that their composition is "as close to the natural organ [the portion of a bone that articulates with the other bone in the joint and is covered with cartilage] as possible." Applicant seems to allege that Jakob's teaching of a construct isolated from natural sources that comprises opposing bone and cartilage sides teaches away from the same composition produced *in vitro* (Reply, page 9, last two paragraphs continuing to page 10), even though applicant stipulates that culturing bone cells and cartilage cells *in vitro* was known in the art at the time of the invention (Reply, page 10, paragraph 2). Applicant alleges that the "interlocking zone" in their construct is "a non-natural feature" with properties that are distinct from the natural product of Jakob (Reply, page 10, paragraph 4). Applicant points to "difficulties in culturing animal cells in the laboratory" as evidence of patentability (Reply, page 9, paragraph 5). These arguments have been fully considered, but they are not persuasive.

As discussed at length in previous Office actions and in the interviews with applicant's representative, the instant claims are drawn to a composition, not to any method of making the same. Furthermore, as pointed out above in the rejections under section 112, claim 36 is not in proper product-by-process form.

Applicant's arguments are contradictory and confusing. Applicant alleges that "difficulties in culturing animal cells in the laboratory" support the patentability of the instant composition (page 9, paragraph 5), but applicant goes on later in the reply to stipulate that they do not "contend that they are the first to culture bone cells or cartilage

cells. Nor do the Applicants suggest that they are the first to realize that animal cells in general are anchorage dependent" (Reply, page 10, paragraph 2). Applicant cannot simultaneously point to the alleged unpredictability of the tissue culture art and later admit on the record that culturing bone and cartilage cells was routine at the time of the invention.

Furthermore, applicant points out numerous times that the claimed construct is identical to the product isolated from natural sources taught by Jakob (page 9, last two paragraphs continuing to page 10; and page 10, paragraph 5) but also alleges that the composition lacks some properties of a natural product (page 10, paragraph 4). These comments are contradictory.

Applicant's allegations about the "interlocking zone" at page 10, paragraph 4, of the comments are not persuasive. The claims do not require an "interlocking zone" *per se* be present in the composition, so applicant is commenting on features that are not claimed. Furthermore, the claims do not preclude the presence of "the nerves, gross histological components, connective tissues, and vascularization of a natural joint" in the composition. As discussed above and previously, claim 36 employs open claim language ("comprising" and "consisting essentially of," which is interpreted here as "comprising" because the specification does not define the basic and novel characteristics of the composition). Because the claim is not a proper product-by-process claim, there is no reason to interpret it as such, *e.g.*, "a composition made by seeding bone cells *in vitro* onto one side of a scaffold and seeding cartilage cells *in vitro* onto the opposing side of said scaffold, then culturing the resulting seeded scaffold for

some period of time to yield a joint construct." This interpretation seems to be what applicant advocates, but the claims are not drawn as such.

Applicant's comments imply that the teaching of a natural product by Jakob teaches away from mimicking that natural product using *in vitro* tissue culture techniques. It is acknowledged that the prior art as a whole must suggest the desirability of the invention, but a finding that the prior art as a whole suggests the desirability of a particular combination need not be supported by a finding that the prior art suggest that the combination claimed is the preferred, or most desirable combination. The prior art's mere disclosure of more than one alternative does not constitute a teaching away from the claimed invention because such disclosure does not criticize, discredit, or other wise discourage the solution claimed in the patent application. See *In re Fulton*, 391 F.3d 1195, 73 USPQ2d 1411 (2004). In this case, the fact that Jakob teaches a construct having the same properties as the claimed construct that is isolated from natural sources is not a teaching away from the tissue engineering art. Tissue engineering *per se* was well known at the time of the invention; indeed, the goal of tissue engineering is to artificially produce tissues that can substitute *in vivo* for natural tissues.

In summary, this rejection is based on the well known teachings of the prior art that bone and cartilage cells may be cultured *in vitro* on the same type of scaffold and that compositions comprising bone on one side and cartilage on the opposing side are useful for treating bone defects. Applicant has not provided arguments or evidence to support the nonobviousness of combining these teachings as set forth by the examiner, *e.g.* a showing of secondary considerations or a persuasive argument that the cited

prior art is non-analogous. See *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 (U.S. 2007).

Claim 37 remains rejected under 35 U.S.C. 103(a) as being unpatentable over Itay, Mikos, Rosenthal et al., and Jakob et al. as applied to claims 36, 38, 41, 42, 44, 67, and 68 above, and further in view of Goldstein et al. (1999, U.S. Patent 5,962,427) and Vacanti et al. (1998, U.S. Patent 5,804,178).

The teachings of Itay, Mikos, Rosenthal et al., and Jakob et al. are relied upon as above. Furthermore, Itay teaches that the *in vitro* cartilage composition may include progenitor cells of mesenchymal origin, bone marrow stromal cells, or any undifferentiated mesenchymal cells (column 3, lines 35-46) and may include additional active agents including serum (column 3, lines 47-52).

Itay, Mikos, Rosenthal et al., and Jakob et al. do not teach or suggest including a growth factor that promotes angiogenesis or including endothelial cells or their progenitors in the composition.

Goldstein et al. teach that including DNA encoding vascular endothelial growth factor (VEGF) in an implanted biocompatible matrix promotes angiogenesis at the implant site by transfecting nearby cells (column 2, lines 21-36; column 14, lines 13-45; and column 24, lines 7-29). The matrix of Goldstein et al. may be any biodegradable matrix (column 11, line 19, through column 14, line 4), including PGA (column 12, line 35). Goldstein et al. also teach administering recombinant VEGF protein (column 2, line 42, through column 3, line 31).

Vacanti et al. teach implanting endothelial cells in a biodegradable matrix such as PGA (Abstract; column 3, lines 5-41; column 4, lines 52-57; column 5, lines 49-50).

A person of ordinary skill in the art would have had a reasonable expectation of success in including either pro-angiogenic growth factors (such as VEGF) or cells carrying cDNAs therefor or endothelial cells *per se* (which are required structural components of blood vessels) in the composition of Itay in view of Mikos, Rosenthal et al., and Jakob et al. because Itay suggests including additional cell types and additional active agents and because Goldstein et al. and Vacanti et al. teach that VEGF protein, VEGF cDNA, cells transfected with VEGF cDNA, and endothelial cells may be implanted using a biocompatible matrix equivalent to those employed by Itay and Mikos. The skilled artisan would have been motivated to include endothelial cells and/or pro-angiogenic growth factors for the expected benefit of increasing the degree of vessel formation around the implant after it has been placed into a recipient, thus improving the implant's ability to incorporate into the recipient's body.

It would therefore have been obvious to a person of ordinary skill in the art at the time the invention was made to include the pro-angiogenic factors of Goldstein et al. or the endothelial cells of Vacanti et al. in the composition of Itay taken in view of Mikos, Rosenthal et al., and Jakob et al. because Goldstein et al. and Vacanti et al. teach that these components improve angiogenesis upon implantation of such a composition, thus increasing the chance that the composition successfully engrafts in a patient.

Therefore, the invention as a whole would have been *prima facie* obvious to a person of ordinary skill at the time the invention was made.

Applicant alleges that the examiner employed impermissible hindsight in rejecting claim 37 (Reply, page 11, last two paragraphs). Applicants allege that the tissue culture art is unpredictable and urge that if the invention were obvious, the claimed composition would have been made before *(ibid.)*. These arguments have been fully considered, but they are not persuasive.

The examiner's remarks above regarding applicant's arguments against the rejection of claims 36, 38, 41, 42, 44, 67, and 68 also apply to these arguments. Furthermore, applicant's arguments fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references. Applicants have admitted on the record repeatedly that they agree with the examiner's finding that culturing bone and cartilage cells *in vitro* was well known at the time of the invention, and applicants have admitted that the construct has the same configuration as the naturally obtained product of Jakob. Applicants have not provided any evidence, *e.g.* unexpected results or other secondary considerations, that combining the teachings of the prior art would not have been obvious at the time of the invention, as set forth by the examiner; applicants have also not established that the cited prior art is non-analogous. See *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 (U.S. 2007).

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon

hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). In this case, culturing bone and cartilage cells was known in the art at the time the invention was made, as were constructs having bone tissue on one side and cartilage on the opposing side. It is not clear what improper hindsight applicants feel was used in making this rejection, since each and every component of the claimed composition was well known by skilled artisans at the time of the invention.

Claims 39 and 43 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Itay, Mikos, Rosenthal et al., and Jakob et al. as applied to claims 36, 38, 41, 42, 44, 67, and 68 above, and further in view of Wevers (1981, U.S. Patent 4,246,660) and Dunn et al. (1995, *Journal of Biomedical Materials Research* 29: 1363-1371).

The teachings of Itay, Mikos, Rosenthal et al., and Jakob et al. are relied upon as above.

Itay, Mikos, Rosenthal et al., and Jakob et al. do not teach or suggest compositions comprising ligaments or joint capsules.

Wevers teaches a prosthetic ligament device comprising an elastic synthetic woven material, the device being securable to bones by use of bone screws (claim 1 and Figures).

Dunn et al. teach a ligament analog prepared by seeding collagen scaffolds with fibroblasts that approximates the structure and strength of native ligament tissue. The artificial ligament of Dunn et al. remains viable after implantation into a joint.

A person of ordinary skill in the art would have had a reasonable expectation of success in connecting the parts of the bone replacement of Itay taken in view of Mikos, Rosenthal et al., and Jakob et al. with the artificial ligaments of Wevers and Dunn et al. because the artificial ligaments are disclosed as having properties similar to native ligament tissue. The skilled artisan would have been motivated to connect multiple compositions of Itay taken in view of Mikos, Rosenthal et al., and Jakob et al. with the ligament compositions of Wevers and Dunn et al. for the expected benefit of strengthening the replaced joint. The artificial ligament of Wevers in particular is disclosed as having elastic properties closely approximating natural ligament tissue (Figures 2 and 3), so joining the joint replacement elements with the ligament of Wevers would more closely simulate a natural joint (see Abstract).

It would therefore have been obvious to a person of ordinary skill in the art to connect multiple compositions of Itay taken in view of Mikos, Rosenthal et al., and Jakob et al. with ligament compositions in order to stabilize the replacement joint and to simulate more closely the natural properties of the joint.

Therefore, the invention as a whole would have been *prima facie* obvious to a person of ordinary skill at the time the invention was made.

Applicants rely on arguments traversing the above rejection of claim 37 to traverse this rejection (Reply, page 11). Therefore, the response set forth above to arguments also applies to this rejection.

No claims are allowed. No claims are free of the art.

Applicant is requested to **specifically point out the support for any amendments** made to the disclosure in response to this Office action, including the claims (MPEP 714.02 and 2163.06). In doing so, applicant is requested to **refer to pages and line numbers** in the as-filed specification, **not** the published application. Due to the procedure outlined in MPEP § 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 U.S.C. § 102 or 35 U.S.C. § 103(a) once the aforementioned issue(s) is/are addressed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lora E. Barnhart whose telephone number is 571-272-1928. The examiner can normally be reached on Monday-Thursday, 9:00am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Lora E Barnhart

SANDRA E. SAUCIER
PRIMARY EXAMINER